

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NANA K. AYISI

Appeal No. 2006-1608
Application No. 09/978,593

MAILED

SEP 28 2006

U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ON BRIEF

Before SCHEINER, MILLS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 20, 22, 31 and 32, which read as follows:

20. The method according to claim 31, wherein the virus is human immunodeficiency virus (HIV), herpes simplex virus (HSV), human cytomegalovirus (HCMV), poliovirus (PV), measles virus (MV) or yellow fever virus (YMV).
22. The method according to claim 20, wherein the virus is HIV-1, HCMV, HSV-1 or HSV-2.
31. A method comprising: contacting a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell.

32. The method according to claim 20, wherein the virus is HIV.

Claims 20, 22, 31 and 32 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification fails to provide an enabling disclosure. In addition, claims 20 and 31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by El-Said¹ as evidenced by Merck.² After careful review of the record and consideration of the issues before us, we reverse both rejections.

DISCUSSION

Claims 20, 22, 31 and 32 stand rejected under 35 U.S.C. § 112, first paragraph, “because the specification, while being enabling for inhibiting HIV viral replication in Vero cells and Molt4 clone 8 cells with an extract of O. gratissimum, does not reasonably provide enablement for the O. gratissimum extract to inhibit HIV viral replication in a mammal or any other cell line. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.” Examiner’s Answer, page 3.

¹ El-Said et al. (El-Said), “An investigation into the efficacy of Ocimum gratissimum as used in Nigerian native medicine,” Planta Medicine, pages 195-200 (1969).

² Merck Manual (Merck), Beers et al., editors, published by Merck Research Laboratories, Whitehouse Station, NJ, pp. 1293-1296, 1303-1306, 1312-1323, 2320-2324 and 2341-2343 (1999).

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Here, the examiner has not provided "acceptable evidence or reasoning which is inconsistent" with the specification, and therefore has not met the initial burden of showing nonenablement.

While the examiner engages in a Wands analysis, see In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988) (noting that facts that should be considered in determining whether a specification is enabling include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims), the examiner's primary concern

appears to be that “the use of in vitro tests is not an acceptable predictor of in vivo activity when claiming treatments to HIV.” Examiner’s Answer, page 6.

According to the examiner, the “[c]haracteristics of a compound’s activity in vitro using purified or partially purified components generally differs significantly with the compound when used in a living body.” Id. at 3. The examiner asserts that clinical correlation of in vitro activity to in vivo efficacy is generally lacking, as cultured cell lines “differ significantly from in vivo animal models.” Id. at 4.

Moreover, as explained by the examiner, “[t]he greatly increased complexity of the in vivo environment as compared to the very narrowly defined and controlled conditions of an in vitro assay does not permit a single extrapolation of in vitro assays to human diagnostic efficacy with any reasonable degree of predictability.” Id. The examiner cites Planchon,³ Kerr⁴ and Chomienne⁵ to demonstrate the lack of correlation of in vitro testing to in vivo efficacy. See id. at 5. The examiner then cites a statement by Joanne Shellenbach, a spokeswoman for the American Cancer Society, quoted in the

³ Planchon et al. (Planchon), “Differential Effects of Butyrate Derivatives on Human Breast Cancer Cells Grown as Organotypic Nodules In Vitro and as Xenografts In Vivo,” In Vivo, Vol. 6, pp. 605-10 (1992).

⁴ Kerr et al. (Kerr), “The relationship between Cytotoxic Drug Exposure and Tumour Cell Kill, In Vitro and In Vivo,” In Vivo, Vol. 5, pp. 385-88 (1991).

⁵ Chomienne et al. (Chomienne), “Discrepancy Between In Vitro and In Vivo Passaged U-937 Human Leukemic Cells: Tumorigenicity and Sensitivity to Differentiating Drugs,” In Vivo, Vol. 2, pp. 281-88 (1988).

Washington Times,⁶ stating that results in animal models “cannot always be easily replicated in humans.” Id.

The examiner next cites Kirsi⁷ for its teaching that “[t]he effect of an inhibitor is also dependent on the virus, inhibitor concentration and cell line used,” indicating that an “inhibitor may be effective in one cell line but not in another cell line for the same virus.” Id. at 6. Finally, the examiner cites Mitsuya⁸ and Sandstöm⁹ as evidence that a drug that showed promise as a treatment of HIV in vitro, suramin, was not correlated to in vivo efficacy. See id.

The invention that must be enabled to satisfy § 112 is the invention defined by the claims. See CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (“Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.”). Thus, when the claims are not limited to a method that achieves therapeutic or clinical efficacy, such efficacy is not required for the claims to be enabled.

⁶ Joyce Howard Price, Researchers test ‘smart-bomb’ cancer therapy, Washington Times, November 16, 2001, at 3.

⁷ Kirsi et al. (Kirsi), “Broad-Spectrum Antiviral Activity of 2-β-D-Ribofuranosylselenazole-4-Carboxamide, a New Antiviral Agent,” Antimicrobial Agents and Chemotherapy, Vol. 24, No. 3, pp. 353-61 (1983).

⁸ Mitsuya et al. (Mitsuya), “Suramin Protection of T Cells in Vitro Against Infectivity and Cytopathic Effect of HTLV-III,” Science, Vol. 226, pp. 172-74 (1984).

⁹ Sandstöm et al. (Sandstöm), “Antiviral Therapy in AIDS Clinical Pharmacological Properties and Therapeutic Experience to Date,” Drugs, Vol. 34, pp. 372-90 (1987).

Here, the claims are directed to a “method comprising [] contacting a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell” (claim 31). Thus, while it is fair to say that the claims encompass a method that achieves a clinically effective therapeutic response, they do not require it. Cf. In re Cortright, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999) (claims to a method of “treating scalp baldness” could be enabled even if the method did not produce a full head of hair).

We conclude that the potential problems identified by the examiner may indeed complicate treatment of a HIV in a patient, but such problems need not be overcome in order to “contact[] a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell” - all that is required by the claims. Thus, the examiner has not adequately explained why practicing the claimed method would have required undue experimentation.

Moreover, a claim may encompass inoperative embodiments and still meet the enablement requirement of 35 U.S.C. § 112, first paragraph. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976), In re Cook, 439 F.2d 730, 732, 169 USPQ 298, 300 (CCPA 1971). And the stage at which an invention in this field become useful is well before it is ready to be administered to humans.” In re Brana, 51 F.3d 1560,

1568, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995). (While the Brana court referred to “usefulness”, the rejection on appeal was for nonenablement. See id. at 1564, 34 USPQ2d at 1439.)

Therefore, as the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first paragraph, we are compelled to reverse the rejection.

Claims 20 and 31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by El-Said.

According to the rejection,

El-Said [] disclose[s] that an aqueous extract of O. gratissimum has been used in Nigerian herbal medicine for the treatment of fevers (see abstract). Fever is a symptom that is associated with viral or bacterial infections (as evidenced by . . . Merck . . .). Thus, the treatment of viral infection using an extract of O. gratissimum is anticipated by El-Said [].

Examiner’s Answer, page 7.

The burden is on the examiner to set forth a prima facie case of unpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997).

Appellant argues that El-Said “disclose[s] the chemotaxonomy and antibacterial testing of Ocimum gratissimum specimens.” Appeal Brief, page 11 (emphasis in original). Therefore, according to appellant, “[t]he invention, as

claimed, is not anticipated by [El-Said] because the reference does not disclose anti-viral testing and/or a method of use of Ocimum gratissimum for inhibiting the cytopathic effects of a virus-infected cell." Id. at 12. We agree, and the rejection is reversed.

CONCLUSION

Because the examiner has failed to set forth a prima facie case of unpatentability, both rejections of record are reversed.

REVERSED



Toni R. Scheiner
Administrative Patent Judge



Demetra J. Mills
Administrative Patent Judge

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) APPEALS AND

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